# UpSwinG: Real World study on TKI activity in Uncommon mutations and Sequencing Giotrif®

**First published:** 10/03/2020

**Last updated:** 30/10/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS32098

**Study ID**

32099

**DARWIN EU® study**

No

**Study countries**

- Austria
- China
- France
- Germany

Italy

Japan

Korea, Republic of

Spain

Taiwan

United Kingdom

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**Study description**

This is a non-interventional, multi-country, multi-centre study based on existing data from medical records or electronic health records.

The study observes how long patients with non-small cell lung cancer (NSCLC) benefit from treatment with Epidermal Growth Factor Tyrosine Kinase Inhibitor (EGFR-TKI) when given either for uncommon mutations or for common mutations in the sequence afatinib followed by osimertinib.

Total enrolled: at least 200 patients per cohort.

For both cohorts the study aims to describe the time on treatment until its end or death.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Royal Marsden Hospital

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Sanjay Popat

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 06/12/2019

**Study start date**

Planned: 09/12/2019

**Data analysis start date**

Planned: 01/12/2020

**Date of final study report**

Planned: 31/12/2020

Actual: 12/07/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim International

## Study protocol

1200-0316_Prot_redacted.pdf (1.7 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

1200-0316; NCT04179890

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Other

**If ‘other’, further details on the scope of the study**

The study observes how long patients with non-small cell lung cancer (NSCLC) benefit from treatment with Epidermal Growth Factor Tyrosine Kinase Inhibitor (EGFR-TKI).

**Data collection methods:**

Secondary use of data

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**Study design:**

Non-interventional, multi-country, multi-centre study based on existing data from medical records or electronic health records.

**Main study objective:**

The study aims to describe the time on treatment until its end or death.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Non-interventional, multi-country, multi-centre study based on existing data from medical records or electronic health records

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01XE13) afatinib

afatinib

(L01XE02) gefitinib

gefitinib

(L01XE03) erlotinib

erlotinib

(L01XE35) osimertinib

osimertinib

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**Medical condition to be studied**

Non-small cell lung cancer

## Population studied

**Short description of the study population**

Patients with non-small-cell lung cancer (NSCLC)

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Estimated number of subjects**

400

## Study design details

**Setting**

A total of 56 study centers in 9 countries (Austria, France, Germany, Italy, Spain, United Kingdom, Japan, Korea Republic, and Taiwan Republic of China) were initiated in this non-interventional study.

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**Outcomes**

Time on treatment with EGFR-TKI(s), Overall survival, ORR, methodology and material used for mutational testing. Uncommon cohort only: time on treatment until failure of second line (TTF2).

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**Data analysis plan**

The two cohorts will be analysed separately- Uncommon mutations- Sequencing of osimertinib after afatinibThe primary endpoint for both cohorts is time on treatment. Kaplan-Meier estimates will be calculated.

In addition, the median will be tabulated along with the two-sided 95% confidence interval, using Greenwood’s variance estimate.
The primary analysis will be repeated within subgroups.
The following additional endpoints will be analyzed similarly to the primary endpoint.- overall survival- time on treatment until failure of second-line (uncommon cohort only)Patients who were not known to have discontinued

treatment will be censored on the date they were last verified to have been on treatment.
As an additional exploratory analysis, the data from the sequencing cohort of this study may be pooled with the previous GioTag study.

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**Summary results**

Uncommon mutation cohort

Afatinib is the standard of care (SoC) for most patients with uncommon mutations. The study supports the use of afatinib against major uncommon and compound EGFR mutations with additional broad activity against other uncommon EGFR mutations and some exon 20 insertions. It provides insights into treatment and testing strategies and emphasizes the need for broad testing and a clear description of mutations given their heterogeneity.

Sequencing cohort

The main study findings were in line with the expectations and well aligned to those obtained rom the GioTag study, which can now be enriched with the Upswing data (obtained from a cohort composed especially of Asian patients). Therefore, the Upswing study allowed to further investigate the overall benefit for the sequential EGFR TKI treatment with afatinib and osimertinib for the common EGFR mutations.

The ADRs to Giotrif® reported in this study, and their severity were consistent with the known safety profile of afatinib (Giotrif®). There were no new safety observations or concerns identified in this study.

These findings complement the body of evidence in the real world for a better evidence-based therapy decision in NSCLC advanced EGFR mutated setting.

# Documents

**Study results**

1200-0316_Synopsis.pdf (225.61 KB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data sources (types)**

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

Retrospective patient-based data collection from patient's medical records

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No